UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D451245; **FILE SYMBOL/REG. No.**: 94145-E; **PRODUCT NAME**: Inmes S-Metolachlor Technical; **DECISION No.**: 548536; **PC Code(s)**: 108800; **ACTION CODE**: R334; **FOOD Use**: Yes

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DATE: January 22, 2020

SUBJECT: Product Chemistry Review of "Inmes S-Metolachlor Technical" with a New Unregistered Source of the Active Ingredient

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01.23.2020 01.23.20

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HB / RD (7505P)

REGISTRANT: INMES LLC

MRID Number(s): 50750401-50750417

INTRODUCTION:

The registrant has submitted an application for registration of Inmes S-Metolachlor Technical produced by a new unregistered source. In support of this application, the registrant has submitted a Basic CSF dated 1/04/2019, Group A and Group B chemistry data with MRID Nos. 50750401-50750417. The registrant claimed that the product is similar to S-Metolachlor technical with EPA Reg. No. 100-815.

The cited Basic CSF dated 2/19/2016 (Reg. No. 100-815) – Nominal concentration: 96% – Manufacture site: [redacted]

The proposed Basic CSF dated 1/04/2019 (Reg. No. 94145-E) – Nominal concentration: 98.3% – Manufacture site: [redacted]

CITAB has been asked to determine the acceptability of the product chemistry data and the proposed Basic CSF.

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550: (product identity & composition)

The active ingredient was adequately described (MRID 50750401). The nominal concentration of the active ingredient (98.3%) provided on the basic CSF (dated 1/04/2019) is the same as the average derived from the five-batch preliminary analysis results (98.29 %, from Page 7 of 289 in the Confidential Attachment of MRID 50750402). A rationale for setting the nominal value was provided in MRID

50750401. The nominal concentration on the basic CSF concurs with that on the proposed label. The information presented meets the data requirements for 40 CFR 158.320.

830.1600: (description of materials used to produce the product)

Safety Data Sheets (SDSs) of all the starting materials, and their specifications and suppliers were provided in the study (MRID 50750401). The information presented meets the data requirements for 40 CFR 158.325.

830.1620 (description of production process)

A detailed description of the production process, vessels and equipment, in process control measures and a flow chart were included in MRID 50750401. The information presented meets the data requirements for 40 CFR 158.330.

830.1670 (discussion on the formation of impurities)

Potential impurities were identified and quantified as part of the five-batch analysis (MRID 50750402). The formation and identities of the impurities were fully discussed in MRID 50750401. [redacted]mpurities associated to A.I. were present in the concentration greater than 0.1%. One solvent was identified as an impurity of toxicological concern. Its concentration is over 0.1%. The information presented meets the data requirements for 40 CFR 158.335.

830.1700 (preliminary analysis)

Results are presented for a five-batch analysis using HPLC-UV with external standard calibration for the active ingredient and all impurities except solvent residue and water. The content of R-isomer and S-isomer were determined by chiral HPLC/UV. Identity of active ingredient was confirmed against the reference standard and by MS, UV, FTIR and ^{1}H-NMR. Impurities B and C were identified by UV, MS and ^{1}H-NMR. The content of water was determined by Karl Fischer titration. The content of solvent residue was determined by GC/MS at selected ion monitoring mode. The information presented meets the data requirements for 40 CFR 158.345.

830.1750 (certified limits)

The proposed upper and lower certified limits for the active ingredient on the proposed basic CSF (dated 1/04/2019) are within the range of the guideline OCSPP 830.1750 recommendation. The upper certified limits of all impurities are proposed and justified (MRID 50750401). The information presented meets the data requirements for 40 CFR 158.350.

830.1800 (enforcement analytical method)

The analytical method for quantifying the active ingredient in Inmes S-Metolachlor Technical" was HPLC with external standard calibration, which was validated for linearity, selectivity, recovery, repeatability and intermediate precision. (MRID 50750402).

The methods for quantifying impurities B and C were validated in terms of linearity, selectivity, recovery, repeatability, intermediate precision, LOQ and LOD (MRID 50750402).

The methods for quantifying impurity solvent residue were validated in terms of selectivity, linearity, recovery, repeatability, intermediate precision, LOD and LOQ. (MRID 50750403).

All methods are capable of determining whether an ingredient falls within its certified limits. The information presented meets the data requirements for 40 CFR 158.355.

2. Group B guidelines (physical-chemical properties):

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	50750404	A	Gardner number 11 (Orange)
830.6303	Physical state	50750404	A	Transparent Liquid
830.6304	Odor	50750404	A	Characteristic Odor
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions	50750405	A	Product is stable to normal and elevated temperature.
830.6314	Oxidation/reduction: chemical incompatibility	50750406	A	The product was found to be compatible with common oxidizing and reducing agents.
830.6315	Flammability	50750407	A	The flash point 132 °C at atmospheric pressure
830.6316	Explodability	50750417	W	Product does not contain explosive functional group.
830.6317	One Year storage stability	50750416	A	Product is stable in air for at least 2 years under normal conditions of temperature and storage.
830.6319	Miscibility	50750417	N/A	The product is not an emulsifiable liquid to be diluted with petroleum solvents. Therefore, the data requirement is not applicable.
830.6320	One Year corrosion characteristics	50750416	A	There was no perforation, discoloration and darkening of the packaging material (zinc coating iron box).
830.7000	pH	50750408	A	6.16 at 1% (w/v) at 20 °C
830.7050	UV/Visible absorption	50750409	A	The UV-VIS spectrum of the test substance solution in acidic pH presented maximum absorbance in 206 nm and in basic pH, the maximum was in 225 nm.
830.7100	Viscosity	50750410	A	99.07 $mm^2 s^{-1}$, at 20.0 ± 0.1 °C and 28.46 $mm^2 s^{-1}$ at 40.0 ± 0.1 °C
830.7200	Melting point	50750417	Cited	-61.1 °C
830.7220	Boiling point	50750411	A	238.3 °C
830.7300	Density	50750412	A	1.1182 g/mL at 20 °C
830.7370	Dissociation constants in water (DC)	50750417	W	The product does not contain any function group that would dissociate.

GLN	Requirement	MRID	Status	Result or Deficiency
830.7520	Particle size, fiber length, and diameter distribution	50750417	W	Product is not a fibrous material and is not water-insoluble.
830.7550	Partition coefficient	50750413	A	Log Pow 3.469 at 25°C.
830.7840	Water solubility	50750414	A	0.634 $g.L^{-1}$ in water, 1041.5204 $g.L^{-1}$ in acetone and 975.0806 $g.L^{-1}$ in n-hexane
830.7950	Vapor pressure	50750415	A	5.28 mPa (25 °C)
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers requested				

CONCLUSIONS:

The CITAB has reviewed the proposed basic CSF (dated 1/04/2019) and the supporting Group A and Group B data for Inmes S-Metolachlor Technical and has concluded that:

1. The product chemistry Group A data submitted for guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.

2. [redacted]an impurity of toxicological concern derived from solvent, was present in the technical product with a significant quantity (0.17%). The [redacted]evel would be decreased to a lower level when the product was diluted for future end-uses.

3. The product chemistry Group B data are acceptable.

4. The nominal concentration of the active ingredient on the proposed basic CSF is slightly higher than one found on the cited basic CSF with Reg. 100-815 (98.3 vs 96%). The two CSFs share [redacted] identical impurities.

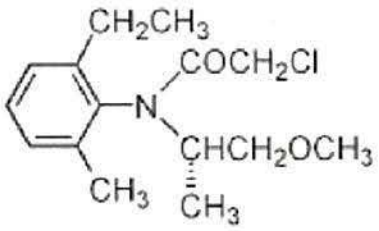
5. The proposed basic CSF (dated 1/04/2019) is acceptable.

Quality control process information may be entitled to confidential treatment

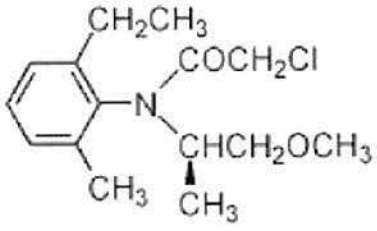
Active Ingredient

INMES S-Metolachlor Technical contains 98.3% S-metolachlor. The CAS No. is 87392-12-9. The CAS nomenclature is (S)- and (R)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide. The Chemical Code is 108800.

The molecular formula for S-Metolachlor is $C_{15}H_{22}ClNO_2$ and the molecular weight is 283.8. The chemical structure is shown below:



(*aRS*,1*S*)-



(*aRS*,1*R*)-

S-Metolachlor

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Confidential Statement of Formula may be entitled to confidential treatment